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CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria VA 22313-1450 on this date.			
Typed or Printed Name		Kimberly Williams Zuehlke	
Signature		<i>Kimberly W Zuehlke</i>	Date 29 July 2003
<b>INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(e)</b>  Address to: Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		Attorney Docket	AERX-088
		First Named Inventor	GONDA, IGOR
		Application Number	09/990,181
		Confirmation No.	1229
		Filing Date	November 21, 2001
		Group Art Unit	1614
		Examiner Name	
		Title: "COMPOSITIONS OF NUCLEIC ACIDS AND CATIONIC AMINOGLYCOSIDES AND METHODS OF USING AND PREPARING THE SAME"	

**RECEIVED**  
AUG 04 2003  
TECH CENTER 1600/2900

Sir:

Applicants submit herewith patents and/or publications which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. While this Statement may be "material" pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication, or other information referred to therein is "prior art" for this invention unless specifically designated as such. A listing of patents and/or publications is shown on enclosed Form PTO-SB/08A and a copy of each patent and/or publication is also enclosed.

Each item of information contained in the Information Disclosure Statement filed herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement (37 C.F.R. 1.97(e)(1)). A copy of the communication is enclosed for the Examiner's convenience.

The Examiner is requested to make the citations listed on the enclosed PTO-SB/08A of record in this application. Applicants would appreciate the Examiner initialing and returning the initialed copy of form PTO-SB/08A, indicating the references have been considered and made of record herein.

No fee is believed due as this statement is being submitted within three months of the mailing date of the enclosed foreign communication. However, if it is determined that fees are required, the Commissioner is hereby authorized to charge any necessary fees associated with this communication or credit any overpayment to Deposit Account No. 50-0815, Order No. AERX-088.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date:

*29/July/03*

BOZICEVIC, FIELD & FRANCIS LLP  
 200 Middlefield Road, Suite 200  
 Menlo Park, CA 94025  
 Telephone: (650) 327-3400  
 Facsimile: (650) 327-3231

By:

*[Signature]*  
 Karl Bozicevic, Reg. No. 28,807

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

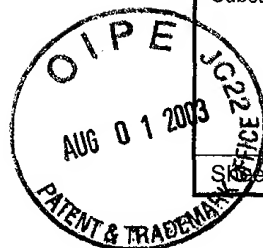
## **Complete if Known**

Application Number 09/990,181  
Filing Date November 21, 2001  
First Named Inventor Igor Gonda  
Group Art Unit 1614  
Examiner Name To Be Assigned  
Attorney Docket Number AERX088

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## **U.S. PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,627,267		Lyman et al.	05-06-1997	
	AB	5,756,353		Debs	05-26-1998	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Documents			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

## **OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AC	Database CAPLUS on STN, AN 1997:345576. PENOLAZZI et al., "Direct transfection of polymerase chain reaction generated fragments into mammalian cells employing ethidium bromide indicator and ultrafiltration." Analytical Biochemistry 1997 Vol. 248, No. 1, pages 190-193, see abstract.	
	AD	ROMANO et al., "Latest Developments in Gene Transfer Technology: Achievements, Perspectives, and Controversies over Therapeutic Applications." Stem Cells. 2000 Vol. 18, pages 19-39, see entire document	
	AE	SOMIA et al., "Gene Therapy: Trials and Tribulations." Nature Reviews/Genetics, November 2000, Vol. 1, pages 91-99, see entire article.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
KARL BOZICEVIC  
BOZICEVIC, FIELD & FRANCIS LLP  
200 MIDDLEFIELD ROAD, SUITE 200  
MENLO PARK, CA 94025

## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

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JUL 24 2003

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Applicant's or agent's file reference  
AERX-088WO

Date of Mailing  
(day/month/year)

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.  
PCT/US02/36529

International filing date  
(day/month/year)

15 November 2002 (15.11.2002)

Applicant  
ARADIGM CORPORATION

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34, chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US  
Commissioner for Patents  
Box PCT  
Washington, D.C. 20231  
Facsimile No. (703)305-3230

Authorized officer

Richard Schnizer, Ph. D

Telephone No. 703-308-1123

to  
Karl  
Bozicevic

DOCKETED 12/25  
Sugr 105 US 12/103

AUG 6 4 2003  
CENTER 1600/2900

*James Bridges*

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
KARL BOZICEVIC  
BOZICEVIC, FIELD & FRANCIS LLP  
200 MIDDLEFIELD ROAD, SUITE 200  
MENLO PARK, CA 94025

## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing (day/month/year) <b>21 JUL 2003</b>	
Applicant's or agent's file reference AERX-088WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US02/36529	International filing date (day/month/year) 15 November 2002 (15.11.2002)
Applicant ARADIGM CORPORATION	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34, chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

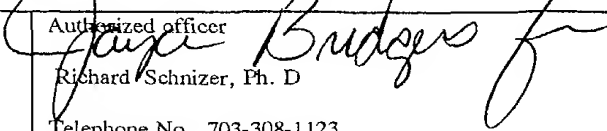
4. **Reminders**

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Commissioner for Patents Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer  Richard Schnizer, Ph. D Telephone No. 703-308-1123
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Form PCT/ISA/220 (April 2002)

(See notes on accompanying sheet)

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference AERX-088WO	<b>FOR FURTHER ACTION</b>	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US02/36529	International filing date (day/month/year) 15 November 2002 (15.11.2002)	(Earliest) Priority Date (day/month/year) 21 November 2001 (21.11.2001)
Applicant ARADIGM CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

#### 1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐

contained in the international application in written form.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority in written form.

☐

furnished subsequently to this Authority in computer readable form.

☐

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

☒

the text is approved as submitted by the applicant.

☐

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒

the text is approved as submitted by the applicant.

☐

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

☐

as suggested by the applicant.

☐

because the applicant failed to suggest a figure.

☐

because this figure better characterizes the invention.



None of the figures

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/36529

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 15/22, 21/02, 21/04; A61K 51/00, 9/66, 9/54; A01N 43/04  
US CL : 536, 13.2, 13.9, 14, 37, 16, 23.1, 23.5, 24.31; 424/1.13; 435/455, 458; 514/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536, 13.2, 13.9, 14, 37, 16, 23.1, 23.5, 24.31; 424/1.13; 435/455, 458; 514/44

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5627267 A (LYMAN et al) 06 May 1997, see paragraph bridging columns 19 and 20.	1-5, 8, 10, 11, 15-19, 25.
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Y		7
Y	Database CAPLUS on STN, AN 1997:345576. PENOLAZZI et al. 'Direct transfection of polymerase chain reaction generated fragments into mammalian cells employing ethidium bromide indicator and ultrafiltration'. Analytical Biochemistry. 1997, Vol. 248, No. 1, pages 190-193, see abstract.	7
A	US 5,756,353 A (DEBS), 26 May 1998, see entire document.	1-28
A	ROMANO et al. Latest Developments in Gene Transfer Technology: Achievements, Perspectives, and Controversies over Therapeutic Applications. Stem Cells. 2000, Vol. 18, pages 19-39, see entire document.	11, 19-28
A	SOMIA et al. Gene Therapy: Trials and Tribulations. Nature Reviews/Genetics. November 2000, Vol. 1, pages 91-99, see entire article	11, 19-28

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 April 2003 (03.04.2003)

Date of mailing of the international search report

21 JUL 2003

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703)305-3230

Authorized officer

Richard Schnizer, Ph. D

Telephone No. 703-308-1123

**INTERNATIONAL SEARCH REPORT**

PCT/US02/36529

**Continuation of B. FIELDS SEARCHED Item 3:**  
STN: medline caplus embase biosis biotechds scisearch  
WEST